REMARKS

This paper is responsive to the non-final Office Action mailed March 23, 2004. Claims 80-91 were pending and under consideration in the present application, and this paper presents no amendments to the claims. Thus, following entry of the present response, Claims 80-91 remain pending and under consideration.

I. The Rejection of Claims 80-91 under 35 U.S.C. § 112, Second Paragraph, as Indefinite Should Be Withdrawn

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In particular, the PTO contends that the methods recited by Claims 80, 83, 86, and 89 do not have a clear point that ties to assessing the effectiveness of protease inhibitor therapy, as recited by the preamble to these claims. In response, Applicants respectfully submit that one of skill in the art can appreciate the metes and bounds of Claims 80-91 and that the skilled artisan can accomplish the object set forth in the preamble, *viz.*, assess the effectiveness of therapy with amprenavir, nelfinavir, and/or indinavir, by performing the step recited by each of Claims 80, 83, 86, and 89. Therefore, Applicants respectfully submit that Claims 80-91 are not indefinite.

A. The Legal Standard

Under 35 U.S.C. § 112, second paragraph, a claim must particularly point out and distinctly claim the subject matter which the applicant regards as his invention. *See* 35 U.S.C. § 112, second paragraph. This statutory mandate is met when "one skilled in the art would understand the bounds of the claim when read in light of the specification." *See Solomon v. Kimberly-Clark Corporation*, 216 F.3d 1372, 1378, 55 USPQ2d 1279, 1282 (Fed. Cir., 2000), quoting *Personalized Media Communications, LLC v. International Trade Commission et al.*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir., 1998). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *See Personalized Media*, 161 F.3d at 705, 48 USPQ2d at 1888, quoting *Miles Lab., Inc. v. Shandon, Inc.* 997 F.2d 870, 238 USPQ2d 1123 (Fed. Cir., 1993).

B. A Skilled Artisan Can Assess the Effectiveness of Antiviral Therapy by Practicing the Methods of Claims 80, 83, 86, and 89

Applicants respectfully submit that one of skill in the art can understand how the step of Claim 80, 83, 86, or 89 allows a practitioner to assess the effectiveness of the particular antiviral therapy recited by the preamble to these claims. In particular, Claims 80, 83, 86,

and 89 each comprise a single step that comprises, *inter alia*, detecting in a sample from an HIV-infected patient the presence of a nucleic acid encoding HIV protease that comprises one or more mutations in certain codons of the HIV protease. This single step addresses the effectiveness of the therapies because the presence of such mutation(s) indicates an increase or decrease in susceptibility to amprenavir, nelfinavir, and/or indinavir, as recited by the claims and demonstrated by the data presented in the present application. *See* Example 4, pages 108-111.

For example, Example 4 at page 109 indicates that the presence of a mutation in codon 88 results in increased amprenavir susceptibility, while mutations at codons 88, 63 and 77 result in reduced susceptibility to nelfinavir and indinavir and increased susceptibility to amprenavir. Thus, if a practitioner detects a mutation in codon 88 of a nucleic acid encoding HIV protease from an HIV-infected patient, the practitioner would recognize that the HIV infecting the patient has increased susceptibility to amprenavir, as recited by the claims. Further, having recognized that the HIV infecting the patient exhibits increased susceptibility to amprenavir, the skilled artisan would be able to assess the effectiveness of therapy with this protease inhibitor. Specifically, the practitioner would recognize that amprenavir therapy had recently been and would be effective.

Similarly, if mutations in codons 88, 63 and 77 were detected in a nucleic acid encoding HIV protease from an HIV-infected patient, the practitioner would recognize that the HIV exhibits reduced susceptibility to nelfinavir and indinavir and increased susceptibility to amprenavir. Accordingly, the skilled artisan would recognize and that nelfinavir or indinavir therapy had recently been and would be ineffective, while amprenavir therapy had recently been and would be effective. In either case, detecting the presence of mutations associated with increased or decreased protease inhibitor susceptibility allows the skilled artisan to evaluate whether therapy with the particular protease inhibitor would be effective.

Thus, detecting the presence of the mutations associated with changes in susceptibility allows the practitioner to assess the effectiveness of protease anti-retroviral therapy, whether, for example, such therapy had been performed in the past, is currently contemplated to be administered, or is contemplated for administration at some point in the future. Therefore, Applicants respectfully submit that the steps of the methods of Claims 80, 83, 86, and 89 in fact allow a skilled artisan to accomplish the purpose set forth in the preambles to these claims. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 80-91 as indefinite under 35 U.S.C. § 112, second paragraph.

II. The Provisional Rejection of Claims 80-91 under the Judicially-Created Doctrine of Obviousness-Type Double Patenting

Claims 80-91 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over Claims 1-12 of U.S. Application No. 09/874,472 ("the '472 application"). Without acquiescing to the propriety of the rejection, Applicants respectfully request, if the only outstanding issue preventing allowance of Claims 80-91 is a provisional obviousness-type double patenting rejection over Claims 1-12 of the '472 application, that Claims 80-91 be passed to issuance and that any non-provisional obviousness-type double patenting rejection be made in connection with the claims of the '472 application rather than the present application. *See* M.P.E.P. § 804 I.B.

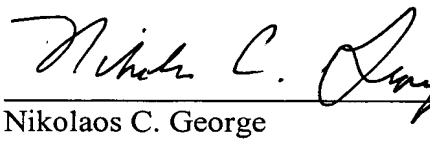
CONCLUSION

In light of the above remarks, Applicants respectfully submit that Claims 80-91 satisfy all the criteria for patentability and are in condition for allowance. Accordingly, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance and solicit an expeditious passage of Claims 80-91 to issuance. The Examiner is invited to call the undersigned attorney at (212) 790-9090, if a telephone call could help resolve any remaining items.

Pursuant to 37 CFR § 1.136(a)(3), the Commissioner is authorized to charge all required fees, fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Jones Day U.S. Deposit Account No. 50-3013 (order no. 101962-999034).

Respectfully submitted,

Date: June 23, 2004



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